

Monsanto

Monsanto Company
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October 28, 1985

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Roundup® Herbicide
EPA Reg. Nos.
524-308, 524-330, 524-332,
524-339, 524-343, 524-351
Addendum to Chronic Mouse
Study with Glyphosate
• Additional Evaluations

Dear Sir:

260623

On July 21, 1983, Monsanto submitted a glyphosate chronic mouse study entitled "A Chronic Feeding Study Of Glyphosate (Roundup® Technical) In Mice (R.D. No. 480 and accession numbers 251007-251014). Subsequently, on July 29, 1985, the Agency requested Monsanto to recut the male mouse kidneys to obtain further information on the presence or absence of kidney tumors. This additional work was completed and submitted on October 7, 1985 to the Agency (R.D. No. 635). It is important to note that these additional data confirm Monsanto's initial position of no treatment related oncogenic effects.

Due to the importance of this chronic mouse study to Monsanto, we requested noted experts (4 individual experts and a consultant panel) to also review these data. They were requested to determine if the effects observed could be considered to be a treatment related oncogenic effect. The conclusions reached by these experts are now being submitted (R.D. No. 643) for Agency information and file use.

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The review results from the independent evaluations of the glyphosate chronic mouse study are the same. Their conclusion is the data reveals no statistically significant difference between any of the treated and control groups, and no statistically significant trend is present.

Based on this information and the previously submitted information which demonstrated that glyphosate did not show a treatment-related oncogenic effect in this chronic mouse study, Monsanto is hopeful that the Agency will reach the same conclusion. In addition, we request that the review of all pending glyphosate petitions now be completed as soon as possible.

Sincerely,



Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich